

Application Serial No. 09/932,494 (Atty. Ref. No. 3320/1/US (PC31245))
Amendment dated November 17, 2005
Reply to Office action dated May 17, 2005

REMARKS

Status of the claims

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 are currently pending. All pending claims stand rejected under §112, first and second paragraphs, as failing to comply with the written description requirement and as being indefinite. All pending claims also stand rejected under §103(a) as unpatentable over Mizumoto et al., U.S. Patent No. 5,576,014 ("Mizumoto") in view of Talley et al., U.S. Patent No. 5,760,068 ("Talley"). Claims 1, 22, 50, and 95 stand rejected under §103(a) as unpatentable over Mizumoto and Talley in view of Jain et al., U.S. Patent No. 6,316,029 ("Jain").

Claims 91 and 101 have been cancelled. Claims 1, 18-21, 46-48, 50-53, 93, 96, and 99 have been amended as follows:

1. Claim 1 has been amended to require the addition of a surfactant.
2. Claim 18-20 and 93 have been amended to depend from claim 1.
3. Claim 21 has been amended to specify antecedent basis for the claim, in light of the amendment of claim 1 as described above.
4. Claims 46-48 have been amended to depend from claim 99, and to specify antecedent basis for the claims in light of the amendment of claim 99 as described below.
5. Claim 50 has been amended to specify antecedent basis for the claim in light of the amendment of claim 96 as described below.
6. Claims 51-53 have been amended to depend from claim 50, and to specify antecedent basis for the claims in light of the amendment of claim 50 as described above.
7. Claim 96 has been amended to specify the antecedent basis for the claim in light of the amendment of claim 99 as described below.
8. Claim 99 has been amended to require that the composition comprises a surfactant.

Support for these amendments may be found, for example, at page 24, line 28 through page 25, line 25. No new matter has been added by these amendments. Applicants reserve the right to pursue any cancelled subject matter in one or more divisional or continuation applications.

Rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §112, first paragraph

Reconsideration is respectfully requested of the rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §112, first paragraph, as failing to comply with the written description requirement. Claims 91 and 101 have been cancelled, rendering moot their rejection under §112, first paragraph..

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The Office asserts that the instant specification does not provide support for the limitation "means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl" in claim 1 and the limitation "a means for inhibiting agglomeration of the drug" in claim 99. Claims 1 and 99 have been amended to cancel these limitations, rendering moot the rejection of the pending claims under §112, first paragraph. Applicants respectfully assert that this amendment has been done in order to advance the prosecution of the instant application, and Applicants respectfully reserve the right to pursue the cancelled subject matter in one or more divisional or continuation applications.

Rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §112, second paragraph

Reconsideration is respectfully requested of the rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §112, second paragraph, as being indefinite. Claims 91 and 101 have been cancelled, rendering moot their rejection under §112, second paragraph.

Claims 1 and 9 have been amended as described above, rendering moot the rejection of the pending claims under §112, second paragraph. Again, Applicants respectfully assert that this amendment has been done in order to advance the prosecution of the instant application, and Applicants respectfully reserve the right to pursue the cancelled subject matter in one or more divisional or continuation applications.

Rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §103(a)

Mizumoto in view of Talley

Reconsideration is respectfully requested of the rejection of claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, and 95-101 under §103(a) as unpatentable over Mizumoto in view of Talley. Claims 92 and 102 have been cancelled, rendering moot their rejection.

Claim 1, as amended, requires a step of adding a surfactant. Similarly, independent claim 99, as amended, requires that the claimed composition comprises a surfactant. Both claims define the surfactant as selected from the group consisting of quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, polyoxyethylene block copolymers, polyoxypropylene block copolymers, polyoxyethylene fatty acid glycerides, polyoxyethylene fatty acid oils, polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids, salts of fatty acids, glyceryl fatty acid esters, sorbitan esters, tyloxapol, and mixtures thereof.

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A *prima facie* showing of obviousness requires, *inter alia*, that the prior art references teach or suggest all the claim limitations. See MPEP §2143. Claims 1 and 99 require a surfactant selected from the group shown above. Mizumoto is silent as to these surfactants, and Talley, taken alone or in combination with Mizumoto, does not describe or suggest all the limitations of claims 1 or 99, or of the dependent claims. Thus, the Office has not shown that claims 1 and 99 are *prima facie* obvious.

Likewise, the Office has not shown that dependent claims 2, 3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-91, 93, 95-98 100, and 101 are *prima facie* obvious, for the same reasons given above for claims 1 and 99, and because of the additional features added by these dependent claims.

Mizumoto and Talley in view of Jain

Reconsideration is respectfully requested of the rejection of claim 1, 22, 50, and 95 as unpatentable over Mizumoto and Talley in view of Jain.

A *prima facie* showing of obviousness also requires that there is some suggestion or motivation to modify the prior art references or combine reference teachings. See MPEP §2143. Applicants respectfully repeat their assertion that there is no suggestion or motivation to combine Mizumoto, Talley, and Jain, and thus that the Office has not shown that claims 1, 22, 50, and 95 are *prima facie* obvious.

Independent claims 1 and 99 have been amended to require a surfactant (as defined in those claims). Applicants repeat their assertion that there is no teaching, suggestion or motivation to combine the cited references to arrive at the claimed compositions, processes, and methods. The Office asserts that "Mizumoto teaches the require [sic] of tableting additives. Jain is relied upon solely for the teaching of tableting additive such as surfactant, including sodium lauryl sulfate." Mizumoto describes certain additives that may be used in his compositions; these include disintegrating agents, binding agents, souring agents, vesicants, artificial sweeteners, perfumes, lubricants, and coloring agents; see col. 13, lines 36-57. Mizumoto demonstrates that his compositions may successfully be prepared without the addition of surfactants (such as the sodium lauryl sulfate and sodium dioxide described by Jain). Similarly, as previously noted, nothing in Jain suggests the need for formulating their poorly soluble drug and surface stabilizer with the saccharide having low moldability and the saccharide having high moldability required by Mizumoto. At the very most, the formulations described by Mizumoto and Jain would be seen as *alternatives* to one another, which one skilled in the art would have no reason or motivation to combine. As such, Applicants respectfully request that the Examiner withdraw the rejection.

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Conclusion

For the foregoing reasons, the Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,



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